IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-JLH
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING/REBIOTIX'S MOTION FOR RECONSIDERATION
REGARDING SUMMARY JUDGMENT OF
PATENT INELIGIBILITY UNDER 35 U.S.C. § 101

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Pursuant to Local Rule 7.1.5(a), Plaintiffs/Counterclaim Defendants Ferring Pharmaceuticals Inc. and Rebiotix, Inc. (collectively, "Ferring") respectfully seek partial reconsideration of the Court's July 30, 2024 order regarding motions for summary judgment. D.I. 421. Specifically, Ferring respectfully requests reconsideration of the portion of that decision concerning Ferring's motion for summary judgment that the asserted claims of United States Patents Numbers 10,675,309 (the "'309 patent") and 11,541,080 (the "'080 patent") (collectively with the '309 patent, the "Borody patents") are unpatentable under 35 U.S.C. § 101.

I. BACKGROUND

On December 8, 2023, Ferring moved for summary judgment that the asserted claims of the Borody patents were unpatentable because they claim ineligible subject matter under Section 101. D.I. 256; D.I. 258 at 30-36; D.I. 295 at 16-19. The Court held a combined pretrial conference and hearing on dispositive motions on July 23, 2024. D.I. 326. At that time, the Court indicated that it had determined that the asserted claims were not directed to a natural product, and therefore, Ferring's challenge to the Borody patents under Section 101 failed as a matter of law under Step 1 of the *Alice*/*Mayo* two-step framework. Ex. 1 (Pretrial Conf. Tr.) at 51:7-52:18. On July 30, 2024, the Court issued an order adopting its rationale from the pretrial conference and denying Ferring's motion for summary judgment. D.I. 421 at 2.

II. SUMMARY OF ARGUMENT

The Court's decision on summary judgment reflects certain clear errors of both law and fact. First, the Court considered only whether the claimed invention has any differences from natural compositions, not whether the claimed inventions were markedly different. Second, the Court did not consider whether any purported significant utility of the claimed inventions was linked to those marked differences or was actually claimed. Third, the Court did not consider the full scope of the claims, which includes compositions with de minimis amounts of a

cryoprotectant and/or antioxidant, when determining whether unpatentable subject matter was included. And fourth, the Court ignored that it is uncontested that natural stool compositions have the same properties and utility as the claimed invention.

It is undisputed that natural human stool can be mixed with nothing more than water, strained, and frozen for significant periods of time in containers adapted to provide enemas without sacrificing efficacy in preventing the recurrence of *C. difficile* infections. This is the only required functionality of the claimed compositions, and therefore, neither cryoprotectant nor antioxidant can be said to confer markedly different characteristics from the natural product (human stool), especially if present in only de minimis amounts. Thus, the claims cover patent ineligible subject matter under Section 101.

III. STATEMENT OF FACTS

A. The Asserted Claims

Ferring moved for summary judgment of patent ineligibility of claim 11 of United States Patent No. 10,463,702; claims 16 and 21 of the '309 patent; claims 4, 8, and 14 of United States Patent No. 11,491,193; and claims 2, 5, and 9 of the '080 patent. D.I. 256 at 4. However, Defendants/Counterclaim Plaintiffs Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC (collectively, "Finch") and Counterclaim Plaintiff/Reply Defendant the Regents of the University of Minnesota ("UMN") (collectively with Finch, "Finch/UMN") have since narrowed the list of asserted claims of the Borody patents to just claims 16 and 21 of the '309 patent and claims 2 and 9 of the '080 patent. D.I. 457 at 7-8. Therefore, only those claims, all of which are directed to in essence pharmaceutical compositions rather than methods of manufacture, will be addressed in this motion for reconsideration.

1. '309 Patent – Claims 16 and 21

The asserted claims of the '309 patent is reproduced below:

> Claim 12 (unasserted). An enema product configured for transporting to a remote facility, the enema product comprising flexible tubing, a sealed bag, and a pharmaceutical composition within the bag, wherein the pharmaceutical composition is formulated for enema delivery from the bag, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a suspension of viable non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the fecal bacteria are separated from rough particulate matter and are not cultured, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of C. difficile infection.
>
> Claim 16. The enema product of claim 12, wherein the cryoprotectant comprises polyethylene glycol.
>
> Claim 21. The enema product of claim 12, wherein the pharmaceutical composition further comprises an antioxidant.

2. '080 Patent – Claims 2 and 9

The asserted claims of the '080 patent are reproduced below:

> Claim 1 (unasserted). An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a sealed container, a tubing equipment, and a pharmaceutical composition within the sealed container, wherein the pharmaceutical composition is formulated for enema delivery from the sealed container via the tubing equipment, wherein the pharmaceutical composition comprises a microbiota suspension comprising a cryoprotectant and viable uncultured non-pathogenic fecal bacteria from a stool of a human donor that has been prescreened for infectious agents, and wherein the pharmaceutical composition is stable during long term storage of the sealed container when frozen.
>
> Claim 2. The enema delivery system of claim 1, wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen or exposed to air.
>
> Claim 9. The enema delivery system of claim 1, wherein the pharmaceutical composition further comprises antioxidants.

B. Natural Characteristics of Fecal Bacteria and Stool Preparations

It is uncontested that untreated human stool can be mixed with nothing more than plain water, have its solids strained, and then be stored frozen for an extended period of time in

enema-ready containers without sacrificing its utility in preventing the recurrence of *C. difficile* infections. This is confirmed by the "Frozen vs Fresh" article cited in Ferring's summary judgment briefing, *see* D.I. 264, Ex. 51, and even Finch/UMN admits that "it is 'undisputed' that cryoprotectants and antioxidants are unnecessary for preserving clinical efficacy." D.I. 281 at 32.

The protocol used when comparing the efficacy of frozen stool samples versus fresh stool samples for fecal microbiota transplantation ("FMT") in "Frozen vs Fresh" is instructive:

> Fresh stool samples from healthy donors were transported to the processing laboratories within 5 hours of collection and stored at 5°C until frozen or used for FMT. Approximately ***100 g of stool sample*** was diluted with ***300 mL of commercially bottled water*** and emulsified using a sterile wooden spatula. Gauze was placed on top of an empty container to ***strain the solids***, and the suspension in the container was ***aspirated into 60-mL syringes, which were also used to administer the enemas***. Patients randomized to receive fresh FMT received the suspension within 24 hours of collection; those randomized to receive the frozen FMT received the suspension within 24 hours of thawing. ***Frozen suspensions were kept at -20°C for a maximum of 30 days and thawed overnight at 25°C; anaerobic bacteria counts have been found to remain stable for at least 30 days when stored at -20°C***.

D.I. 264, Ex. 51 at FER_RBX03012342-43 (emphasis added). This study, which combined human stool with just bottled water prior to freezing, found that "[a]mong adults with recurrent or refractory CDI, the use of frozen compared with fresh FMT did not result in worse proportion of clinical resolution of diarrhea." *Id.* at FER_RBX03012347.

Moreover, the authors of "Frozen vs Fresh" recognized "a number of advantages" associated with using frozen FMT: "less cost with reduction in number and frequency of donor screenings; immediate availability of FMT; and the possibility of delivering FMT at centers that do not have on-site laboratory facilities." D.I. 264, Ex. 51 at FER_RBX03012342.

C. The Court's Order

The Court's order on Ferring's motions for summary judgment issued on July 30, 2024.

D.I. 421. The Court denied Ferring's motion for summary judgment that the asserted claims of the Borody patents are unpatentable under Section 101 and stated that "[t]he parties should consult the transcript of the hearing for a full understanding of these rulings." *Id.* at 2.

The Court's rationale provided at the pretrial conference indicated that "[t]he Federal Circuit tells us that a claim to a manufacturer or composition of matter made from a natural product not directed to the natural product where it has different characteristics and potential for significant utility." Ex. 1 at 51:24-52:3. The Court also found that "[t]he asserted claims here are directed to compositions and methods of manufacturing compositions that incorporate fecal bacteria or microbiota which are a natural product, but the claims also require the addition of a cryoprotectant and/or an antioxidant and an enema container with specific physical characteristics, and I conclude that they're not directed to ineligible subject matter as determined by this -- the Alice test at Step 1." *Id.* at 52:8-15.

IV. LEGAL STANDARD

Motions for reconsideration are "sparingly granted," Del. L. Rule 7.1.5, but may be granted where there is "a need to correct a clear error of law or fact or to prevent manifest injustice." *Tillman v. Pepsi Bottling Grp., Inc.*, No. CIV.04-1314-SLR, 2008 WL 1987262, at *2 (D. Del. May 7, 2008).

V. ARGUMENT

A. The Court's decision reflects clear errors of law.

The Court relied on *Natural Alternatives* for the standard to determine patent eligibility, stating that a claimed invention is "not directed to the natural product where it has different characteristics and potential for significant utility." Ex. 1 at 51:22-52:7 (citing *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019). But the standard is higher. The Supreme Court and Federal Circuit repeatedly have made clear that the proper test is

whether the claimed invention is one having "***markedly*** different characteristics from any found in nature and one having the potential for significant utility." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (emphasis added). Furthermore, the case law requires that the claims incorporate limitations regarding the markedly different characteristics and added utility over the natural product for such features to be considered under the Section 101 analysis. *ChromaDex, Inc. v. Elysium Health, Inc.*, 561 F.Supp.3d 460 (D. Del. 2021) ("the characteristics of the isolated NR in milk—i.e., stability, bioavailability, sufficient purity, and therapeutic efficacy—are immaterial to the *Alice* inquiry because none of these characteristics are required by the claims"); *Regenxbio, Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1226-RGA, 2024 WL 68278, at *5-6 (D. Del. Jan. 5, 2024) (rejecting Plaintiffs' argument that "there is nothing in the legal standard requiring the 'significant utility' be recited in the claims"). Applying the correct legal standard, the facts of this case dictate unpatentability.

The Court's decision also fails to consider the breadth of the asserted claims, all of which are sufficiently broad to cover fecal microbiota preparations containing any amount of a cryoprotectant (claim 16 of the '309 patent and claim 2 of the '080 patent) or antioxidant (claim 21 of the '309 patent and claim 9 of the '080 patent). None of the asserted claims require an ***effective amount*** of a cryoprotectant or antioxidant to provide any added utility, and even Finch/UMN admits that "it is 'undisputed' that cryoprotectants and antioxidants are unnecessary for preserving clinical efficacy." D.I. 281 at 32. The claims' failure to require an effective amount of a cryoprotectant and/or antioxidant to change the composition to something with markedly different characteristics and/or utility is fatal to their patentability.

In particular, critical to the Federal Circuit's rationale in *Natural Alternatives* was the fact that the claims in question required an effective amount of the active ingredient to provide utility

not present in the naturally occurring base compound. 918 F3d at 1343. Subsequent decisions have confirmed that *Natural Alternatives* should be limited to instances in which claims specifically require effective amounts of an active ingredient or other component to markedly change the characteristics of the composition. For example, the Federal Circuit's decision in *ChromaDex*, which closely mirrors the facts of the instant case, found *Natural Alternatives* "particularly instructive" because the asserted claims in there required the "natural products" to be not only isolated but also present in sufficient quantities to "effectively increase[] athletic performance" in a way the naturally occurring product did not. *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280, 1284 (Fed. Cir. 2023). But here, as in *ChromaDex*, the claims do not include any requirement that the composition be effective to do anything beyond what the naturally occurring product already can do. *See id.* Therefore, the claimed invention is not "markedly different" from the natural product, nor does it result in significant utility. *Id.*

Because the Court did not consider the proper legal standard, and because uncontroverted evidence establishes that the claimed invention does not have markedly different characteristics or significant utility beyond that provided by natural stool mixed with water, Ferring respectfully requests that the Court reconsider its decision denying summary judgment of patent ineligibility of the asserted claims of the Borody patents. Moreover, because the asserted claims fail under the "markedly different characteristics" framework, the asserted claims are unpatentable, and the Court need not separately consider the *Alice*/*Mayo* two-step framework. *ChromaDex*, 59 F.4th at 1285; *Regenxbio*, 2024 WL 68278 at *6. However, to the extent the Court does so, the claims are unpatentable under the second step of the *Alice*/*Mayo* framework for the reasons provided in Ferring's summary judgment briefing. D.I. 258 at 30-36; D.I. 295 at 16-19.

B. The Court's decision also reflects clear errors of fact.

The Court's decision on summary judgment also evinces clear errors in applying the facts

of this case to the correct legal standard. The Court did not consider whether any alleged differences between the claimed invention and the natural product (human stool) were significant, nor did the Court consider whether the claims actually require any such difference(s). They do not.

This is confirmed by the "Frozen vs Fresh" article: human stool can be mixed with nothing more than bottled water—both natural products—have the solids drained, and be stored frozen in syringes used to administer enemas for prolonged periods of time without sacrificing efficacy in preventing recurrent *C. difficile*. D.I. 264, Ex. 51 at FER_RBX03012342-343, 347. Such preparations are undoubtedly natural products, and the claimed invention is not markedly different, nor does it have significant additional utility. In particular, nothing in the summary judgment record supports the idea that the addition of de minimis amounts of a cryoprotectant or antioxidant results in markedly different characteristics of the slurry containing the fecal bacteria—nor does the Court's opinion identify any such characteristics. Similarly, the Court does not identify any added utility that is required by the claims, and the "Frozen vs Fresh" article confirms that even those alleged benefits that do not appear in the claims—such as having ready-made FMT samples available on-hand, reducing the number and frequency of donor screenings, and delivering FMT to remote locations—all can be accomplished without the addition of cryoprotectants or antioxidants. D.I. 264, Ex. 51 at FER_RBX03012342

1. The asserted claims of the '309 patent are invalid under Section 101.

Unasserted claim 12 of the '309 would read on the stool samples described in the "Frozen vs Fresh" article, with the exception that those samples were stored in syringes used for enema delivery rather than an enema bag and that claim 12 requires the use of saline instead of water and the inclusion of a cryoprotectant. The district court decision in *ChromaDex* makes clear that simply including a natural product in a standard pharmaceutical formulation does not render it

patent eligible. 561 F.Supp.3d 460, 462, 466-67 (D. Del. 2021). The dependent claims in that case were directed to standard dosage forms, but "the Supreme Court has made clear that more than 'apply it' is needed to 'transform an unpatentable law of nature into a patent-eligible applicable of such a law.'" *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Lab's, Inc.*, 566 U.S. 66, 72 (2012). Thus, neither swapping saline (a natural product) for water (another natural product) nor putting the composition in an enema bag can confer patentability. And claim 12 encompasses compositions with a de minimis amount of a cryoprotectant.

Finch/UMN has never argued that de minimis amounts of a cryoprotectant would change the properties of the claimed composition or result in increased utility. This is especially true for the claims of the '309 patent, ***which do not even require freezing***. Instead, Finch argues solely that a POSA would not add only a de minimis amount of a cryoprotectant. D.I. 281 at 32. Even if true, this does not change the literal scope of the claims. And if "the claims are broad enough to encompass a product of nature, [they are] invalid under § 101." *ChromaDex*, 59 F.4th at 1284. In its decision, the Court did not account for the breadth of the asserted claims and the fact that they encompass compositions having even a de minimis amount of a cryoprotectant.

Asserted claim 16 further specifies that the cryoprotectant is polyethylene glycol, but as with cryoprotectants more generally, Finch/UMN have not and cannot assert that de minimis amounts of polyethylene glycol result in "markedly different" characteristics in the context of the claimed invention, or that such compositions could be useful for ***claimed*** purposes in a manner that natural compositions of stool and saline or water would not be. The same is true with respect to claim 21, which encompasses the inclusion of a de minimis amount of an antioxidant.

2. The asserted claims of the '080 patent are invalid under Section 101.

The asserted claims of the '080 patent are invalid for failing to claim eligible subject matter for the same reasons identified above with respect to the asserted claims of the '309

patent. Although the asserted claims of the '080 patent purport to claim a "system," the Court recognized that "[t]he asserted claims are directed to compositions." Ex. 1 at 52:8-9. The asserted claims of the '080 patent further require that the composition remain "stable during long term storage of the sealed container when frozen" (unasserted claim 1) and "wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen ***or*** exposed to air" (asserted claim 2), but "anaerobic bacteria counts have been found to remain stable for at least 30 days when stored at -20°C" even when fresh stool is mixed with just water, stored in a syringe, and then frozen. D.I. 264, Ex. 51 at FER_RBX03012343. Thus, Finch/UMN cannot claim that a cryoprotectant or antioxidant is necessary to protect the fecal bacteria, particularly when the asserted claims do not require any specific amount or functionality associated with those components. While the inclusion of specific cryoprotectants and/or antioxidants in specific amounts might further protect the fecal bacteria in certain situations, the Borody patents do not claim or require ***effective amounts*** of a cryoprotectant and/or antioxidant to achieve specific improvements over natural stool. Thus, the asserted claims are sufficiently broad to encompass embodiments that are not patent eligible, and therefore, the entire claims fail under Section 101.

C. Correction of these errors is necessary in the interest of justice.

Because the asserted claims of the Borody patents are not eligible for patent protection, it would be a manifest injustice to allow Finch/UMN to assert them against Ferring. Therefore, the Court should reconsider its decision on summary judgment on these issues.

VI. CONCLUSION

For the reasons set forth above, Ferring respectfully requests that the Court reconsider its order denying Ferring's motion for summary judgment that the asserted claims of the Borody patents are not eligible for patent protection under Section 101, and find those claims invalid.

Dated: August 13, 2024

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